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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATEL, JOY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,230	HERBERT ET AL.	
	Examiner	Art Unit	
	Joy P. Patel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/16/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "distal end 121 of delivery device" (Paragraph 87, Line 1) must be shown or the feature(s) canceled from the claim(s). The distal end is mentioned in the specifications as being element 121 of figure 19. However, element 121 is not found in any of the drawings. No new matter should be entered.

   Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: minor grammatical errors and a lack of definition for elements 64 and 66 in the drawings. In paragraph 4, lines 5-7, the term "for example" has been used twice in two consecutive sentences. It is suggested that "For example, some patients may experience symptoms similar to gastroparesis for a short time. For example, patients may experience nausea and vomiting for a short time following surgery" be changed to "For example, some patients may experience symptoms similar to gastroparesis, such as nausea and vomiting for a short time following surgery" or something similar. On paragraph 49, line 2, it is suggested that the word "form" be changed to "from". On paragraph 58, line 5, "device 37" has been written twice. It is suggested that the first "device 37" be removed. In figure 4, elements 64 and 66 have been labeled, however these elements have not been disclosed in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1,2, 6-11, 13, 15, 19-21, 24,25,27,28, 30, 32, 34-36, 39-46, 48, 50-52 55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Swoyer et al (US 6,754,536).

4. In regard to claim 1, In lines 1-5 of the abstract, Swoyer discloses "A GI tract stimulator and/or monitor IMD comprising a housing enclosing electrical stimulation and/or monitoring circuitry and a power source and an elongated flexible member extending from the housing to an active fixation mechanism adapted to be fixed into the GI tract wall..." In lines 18-25 of the abstract, Swoyer further discloses "A first stimulation/sense electrode is preferably an exposed conductive portion of the housing that is aligned with the bend of the flexible member so that it is pressed against the mucosa. A second stimulation/sense electrode is located at the fixation site.

5. In regard to claim 2, Swoyer discloses, "The housing (42) is preferably substantially cylindrical having a length greater than its diameter and can have flattened sides". (Column 8, lines 57-59).

6. In regard to claim 6, Swoyer discloses, "Suction can be confined within a recess of the plate (64). For example, a pair of suction lumens (80) and (82) are depicted in the cross-section view of Fig. 11" (Column 11, lines 13-15).

7. In regard to claims 7 and 27, Swoyer discloses, "In Fig. 8, two (or more) barbed hooks (90,92) project from the plate (64), and the barbed hooks (90,92) engage sub-mucosal tissue to hold the plate (64) against the mucosa (Column 10, line 67 and Column 11, lines 1-3) (Also see figure 8).
8. In regard to claim 8, Swoyer discloses, "The active fixation mechanism are selected from helixes and barbed hooks or pincers or the like having sharpened tips or free ends that perforate the mucosa..." (Column 11, lines 25-27) "The fixation hooks or helixes functioning as stimulation/sense electrodes can be formed of bio-compatible conductive materials that are exposed entirely or selectively insulated in portions thereof...." (Column 11, lines 35-38).
9. In regard to claim 9, Swoyer discloses, "The active fixation mechanism are selected from helixes and barbed hooks or pincers or the like having sharpened tips or free ends that perforate the mucosa and lodge in the muscularis externa or the submucosa..." (Column 11, lines 25-28).
10. In regard to claims 10 and 28, Swoyer discloses, "The fixation hooks or helixes functioning as stimulation/sense electrodes can be formed of bio-compatible conductive materials that are exposed entirely or selectively insulated in portions thereof...." (Column 11, lines 35-38).
11. In regard to claim 11, Swoyer discloses, "In particular reference to the helix (62), it is screwed into the mucosa and sub-mucosal tissue by rotating the esophageal catheter (24) or by rotating the push member (80) as shown in Figs 5 and 7

(Column 10, lines 22-25). Figures 5 and 7 clearly show the "screw-like extension" (the helix) at the distal end of the device housing.

12. In regard to claims 13 and 30, Swoyer discloses, "...invention comprises a hermetically sealed housing enclosing electrical stimulation and/or monitoring circuitry and a power source..." (Column 5, lines 20-22).

13. In regard to claims 15 and 32, Swoyer discloses, "The active fixation mechanism are selected from helixes and barbed hooks or pincers or the like having sharpened tips or free ends that perforate the mucosa..." (Column 11, lines 25-27). "The fixation hooks or helixes functioning as stimulation/sense electrodes can be formed of bio-compatible conductive materials that are exposed entirely or selectively insulated in portions thereof...." (Column 11, lines 35-38).

14. In regard to claims 19 and 34, Swoyer discloses, "For temporary use, the fixation mechanism can be made of a material that is degraded by stomach acid over time to release the GI tract stimulator or monitor IMD and allow it to pass through the GI tract (Column 6, lines 23-26).

15. In regard to claims 20 and 35, Swoyer discloses, "One or more sensor can also be built into the GI tract stimulator or monitor IMD (40) for sensing physiologic parameters including...gastric reflex symptoms, regurgitation, symptoms, bloating, or other conditions known in the art... (Column 12, lines 10-16).

16. In regard to claims 21 and 36, Swoyer discloses, "Symptoms of gastroparesis may range from early satiety and nausea in mild cases to chronic vomiting, dehydration, and nutritional compromise in severe cases" (Column 1, lines 42-

44). Swoyer further discloses, "One or more sensor can also be built into the GI tract stimulator or monitor IMD (40) for sensing physiologic parameters including...gastric reflex symptoms, regurgitation, symptoms, bloating, or other conditions known in the art... (Column 12, lines 10-16).

17. In regard to claim 24, Swoyer discloses, "The GI tract stimulator or monitor IMD (40), includes a telemetry transceiver and antenna (which can be embedded in the elongated flexible member (50), or which can constitute the member (72) or conductor (70)) for communication with external medical devices or programmers in a manner well known in the art" (Column 12, lines 26-31). The use of telemetry eliminates the need to have any leads extend outside of the body of a patient.

18. In regard to claim 25, Swoyer discloses, "A GI tract stimulator and/or monitor IMD comprising a housing enclosing electrical stimulation and/or monitoring circuitry and a power source and an elongated flexible member extending from the housing to an active fixation mechanism adapted to be fixed into the GI tract wall..." (Abstract, lines 1-5). Swoyer further discloses "A first stimulation/sense electrode is preferably an exposed conductive portion of the housing that is aligned with the bend of the flexible member so that it is pressed against the mucosa. A second stimulation/sense electrode is located at the fixation site (Abstract, lines 18-25). Swoyer further discloses, "Symptoms of gastroparesis may range from early satiety and nausea in mild cases to chronic vomiting, dehydration, and nutritional compromise in severe cases" (Column 1, lines 42-

44). Swoyer further discloses, "One or more sensor can also be built into the GI tract stimulator or monitor IMD (40) for sensing physiologic parameters including...gastric reflex symptoms, regurgitation, symptoms, bloating, or other conditions known in the art... (Column 12, lines 10-16).

19. In regard to claim 39, Swoyer discloses, "a hermetically sealed housing enclosing electrical stimulation and/or monitoring circuitry and a power source and supporting a first stimulation/sense electrode adapted to press against the mucosa of the stomach wall" (Column 5, lines 31-35). Swoyer further discloses, "In use, the GI tract stimulator or monitor IMD is fitted into the lumen of an esophageal tube or catheter with the fixation mechanism aimed toward the catheter distal end opening ..." (Column 5, lines 58-60). Swoyer further discloses, "The catheter (and endoscope) is inserted through a curved mouth and throat guard inserted into the patient's mouth and the catheter distal end is advanced through the esophagus and lower esophageal sphincter into the stomach cavity." (Column 5, lines 63-67). Swoyer further discloses, "Preferred forms of fixation mechanisms comprise a helix, one or more hook, or clips or pincers that penetrate through the mucosa into the muscularis externa or pinch a fold of the mucosa." (Column 6, lines 8-11). Swoyer further discloses, "The expression "stimulation/sense electrode" as used herein applies to stimulation electrodes that are employed to stimulate tissue or sense electrodes to sense electrical signals..." (Column 6, line 66 – Column 7, line 1).

20. In regard to claim 40, Swoyer discloses, "In use, the GI tract stimulator or monitor IMD is fitted into the lumen of an esophageal tube or catheter with the fixation mechanism aimed toward the catheter distal end opening ..." (Column 5, lines 58-60). Swoyer further discloses, "The catheter (and endoscope) is inserted through a curved mouth and throat guard inserted into the patient's mouth and the catheter distal end is advanced through the esophagus and lower esophageal sphincter into the stomach cavity." (Column 5, lines 63-67).
21. In regard to claim 41, Swoyer discloses, "In one variation described further below, the push member (80) can comprise a vacuum tube that is coupled with a vacuum port and vacuum lumen of the GI tract stimulator or monitor IMD (40) for providing suction at the active fixation mechanism...to draw the mucosa of the stomach wall against the active fixation mechanism...to help effect fixation." (Column 10, lines 1-8). Swoyer further discloses, "The mucosa can be drawn against the esophageal catheter distal end by drawing suction through the catheter lumen. The fixation mechanism is then pushed or screwed into the stomach wall..." (Column 6, lines 11-14).
22. In regard to claims 42, 43, 44, 45, and 46, Swoyer discloses, "The active fixation mechanism are selected from helixes and barbed hooks or pincers or the like having sharpened tips or free ends that perforate the mucosa..." (Column 11, lines 25-27). "The fixation hooks or helixes functioning as stimulation/sense electrodes can be formed of bio-compatible conductive materials that are

exposed entirely or selectively insulated in portions thereof...." (Column 11, lines 35-38).

23. In regard to claim 48, Swoyer discloses, "...a hermetically sealed housing enclosing electrical stimulation and/or monitoring circuitry and a power source ..." (Column 5, lines 21-22; Column 5, lines 31-33).

24. In regard to claim 50, Swoyer discloses, "For temporary use, the fixation mechanism can be made of a material that is degraded by stomach acid over time to release the GI tract stimulator or monitor IMD and allow it to pass through the GI tract (Column 6, lines 23-26).

25. In regard to claims 51, 55, and 56, Swoyer discloses, "One or more sensor can also be built into the GI tract stimulator or monitor IMD (40) for sensing physiologic parameters including...gastric reflex symptoms, regurgitation, symptoms, bloating, or other conditions known in the art... (Column 12, lines 10-16).

26. In regard to claim 52, Swoyer discloses, "Symptoms of gastroparesis may range from early satiety and nausea in mild cases to chronic vomiting, dehydration, and nutritional compromise in severe cases" (Column 1, lines 42-44). Swoyer further discloses, "One or more sensor can also be built into the GI tract stimulator or monitor IMD (40) for sensing physiologic parameters including...gastric reflex symptoms, regurgitation, symptoms, bloating, or other conditions known in the art... (Column 12, lines 10-16).

27. Claims 1,2,9-11,13,15-17,20,21,24,25,28,30,32,36,39,40,45,46,48,51,52,55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Imran et al (US 2004/0088023 A1).

28. In regard to claim 1, Imran discloses, "...a preferred device includes: at least one stimulating electrode in electrical contact with the stomach wall; an electronics unit containing the electronic circuitry of the device; and an attachment mechanism for attaching the device to the stomach wall. One or more stimulating electrodes may be secured to the wall of the stomach by the attachment device. One or more stimulating electrodes may also be located on the electronics unit." (Paragraph 14, lines 3-10). Imran further discloses "The device components are constructed of materials that allow it to withstand and function in the highly acidic environment of the stomach of two or more years.... Such materials are relatively inert to the environment (Paragraph 16, lines 5-7).

29. In regard to claim 2, Imran discloses, "As such, the electronics unit is preferably of a generally cylindrical shape" (Paragraph 16, lines 3-5).

30. In regard to claims 9-11, 15, 28, 32, 45, and 46, Imran discloses, "Anchor (410) comprises a screw connector (411) located on the distal end (413) of the anchor (410). The screw (411) includes electrode (416) coupled by way of a conductor extending through the anchor (410) to electrical contact (418). The distal portion of the screw may include a retaining element (419) to prevent dislodgement of the screw from the stomach wall." (Paragraph 102, lines 1-6) (See figure 32)

31. In regard to claims 13, 30, and 48, Imran discloses, "A preferred embodiment of the electronic circuitry (25) is illustrated in Fig. 25. The electronic circuitry (25) of the stimulator is located in the main housing. The circuitry (25) comprises..., an internal clock (41), and battery device (44) such as a pair of lithium iodine batteries for powering the various components of the circuit (25). As such, the controller (40) and battery device (44) are coupled to each of the major components of the circuit as would be apparent to one of ordinary skill in the art. (Paragraph 81, lines 1-8)

32. In regard to claim 16, Imran discloses, "The main body (20) further comprises an electrode (32) located on the distal face." (Paragraph 61, lines 20-21). Imran further discloses, "...the electrode (126) may be constructed in a manner similar to electrode (32) using a corrosion resistant material that is directly coupled to the electronic circuitry...(Paragraph 63, lines 22-25).

33. In regard to claim 17, Imran discloses, "As such, the electronics unit is preferably of a generally cylindrical shape" (Paragraph 16, lines 3-5). Imran further discloses, "The anchor 123 comprises an elongate member 124 having an expandable distal end 125 and a stimulating electrode 126 in the form of a ring of a corrosion resistant metal conductor such as Platinum, Gold, Tantalum, Titanium or suitable alloys thereof, extending around the elongate member 124 just proximal of the expandable end 125 (Paragraph 59, lines 3-9). See figures 11 and 12.

34. In regard to claim 20, 51, 55, and 56, Imran discloses, "In another variation, the device is designed to stimulate the stomach to delay passage of food from the stomach and into the small intestine. Other stimulation effects are also contemplated, including, but not limited to using stimulation to treat nausea, obesity or pain symptoms." (Paragraph 13, lines 10-13).

35. In regard to claim 21, it is known that vomiting and nausea are symptoms of gastroparesis, pregnancy, chemotherapy, dyspepsia, and post-operative ileus.

36. In regard to claim 24, Imran discloses, "An endoscopic delivery system delivers the functional device through the esophagus and into the stomach, where it is attached to the stomach wall" (Abstract, lines 16-19). Imran further discloses, "The device may also be user controlled, where the recipient of the device is able to externally activate the device, for example by using an external unit which delivers a control signal via telemetry." (Paragraph 20, lines 6-8). Furthermore, none of the illustrations suggest that there are any external components to the device of Imran.

37. In regard to claim 25, Imran discloses, "...a preferred device includes: at least one stimulating electrode in electrical contact with the stomach wall; an electronics unit containing the electronic circuitry of the device; and an attachment mechanism for attaching the device to the stomach wall. One or more stimulating electrodes may be secured to the wall of the stomach by the attachment device. One or more stimulating electrodes may also be located on the electronics unit." (Paragraph 14, lines 3-10). Imran further discloses "The

device components are constructed of materials that allow it to withstand and function in the highly acidic environment of the stomach of two or more years.... Such materials are relatively inert to the environment (Paragraph 16, lines 5-7). Furthermore, Imran discloses, "In another variation, the device is designed to stimulate the stomach to delay passage of food from the stomach and into the small intestine. Other stimulation effects are also contemplated, including, but not limited to using stimulation to treat nausea, obesity or pain symptoms." (Paragraph 13, lines 10-13). Furthermore, it is known that symptoms of gastroparesis include nausea and vomiting.

38. In regard to claim 36, Imran discloses, "In another variation, the device is designed to stimulate the stomach to delay passage of food from the stomach and into the small intestine. Other stimulation effects are also contemplated, including, but not limited to using stimulation to treat nausea, obesity or pain symptoms." (Paragraph 13, lines 10-13). Furthermore, it is known that nausea and vomiting are symptoms of gastroparesis, functional dyspepsia, chemotherapy, post-operative ileus, and pregnancy.

39. In regard to claim 39, Imran discloses, "The functional device in one embodiment provides a device, system and method for gastric electrical stimulation where stimulating electrodes are secured to the wall of the stomach by the attachment device or otherwise. (Abstract, lines 7-10). Imran further discloses, "A preferred device includes: at least one stimulating electrode in electrical contact with the stomach wall; an electronics unit containing the

electronic circuitry of the device..." (Abstract, lines 11-13). Imran further discloses, "An endoscopic delivery system delivers the functional device through the esophagus and into the stomach where it is attached to the stomach wall." (Abstract, lines 16-19).

40. In regard to claim 40, Imran discloses, "An endoscopic delivery system delivers the functional device through the esophagus and into the stomach, where it is attached to the stomach wall" (Abstract, lines 16-19).

41. In regard to claim 52, Imran discloses, "In another variation, the device is designed to stimulate the stomach to delay passage of food from the stomach and into the small intestine. Other stimulation effects are also contemplated, including, but not limited to using stimulation to treat nausea, obesity or pain symptoms." (Paragraph 13, lines 10-13). Furthermore, it is known that nausea and vomiting are symptoms of gastroparesis, functional dyspepsia, chemotherapy, post-operative ileus, and pregnancy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

42. Claims 3,4, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer (US 6,754,536) in view of Kilcoyne (US 2005/0043601 A1). Swoyer is discussed above. Swoyer teaches an implantable gastrointestinal stimulation device, which contains an attachment means that is not directly on the device housing. Kilcoyne teaches a gastrointestinal monitoring device that contains the means of attachment directly on the device housing. This method of attachment allows the Kilcoyne device to be considerably smaller than the Swoyer device. Therefore, it would have been obvious to one skilled in the art to modify the Swoyer device to have the attachment device attached to the device housing (See Kilcoyne Paragraph 16, lines 4-11 and Paragraph 18, lines 1-4).

43. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer (US 6,754,536) in view of Kilcoyne (US 2005/0043601 A1). Swoyer is discussed above. Swoyer teaches that the attachment means can be constructed to operate as electrodes (Column 6, lines 54-57), but fails to make the attachment means a part of the housing. Kilcoyne teaches a device in which the attachment means is a portion of the device housing (See Kilcoyne Paragraph 15, lines 4-11 and Paragraph 18, lines 1-4). Therefore, it would have been obvious to one of ordinary skill in the art to modify the Swoyer device to have an attachment means on the device housing, in which the attachment means could function as an electrode.

44. Claims 12, 29, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer (US 6,754,536) as discussed above, in view of Imran

(US 2005/0090873 A1) and as being unpatentable over Imran (US 2004/0088023 A1) as discussed above, in view of Imran (US 2005/0090873 A1). Imran ('05) teaches a gastrointestinal stimulation device that is composed of "A fixation device for holding stimulating electrodes in electrical contact with the wall of a portion of the gastrointestinal tract" (Abstract lines 1-3). Imran further teaches, "According to another embodiment of the invention, the fixation device comprises a self-expanding tubular member." (Paragraph 7, lines 10-12) (See also figures 1A and 1B). The primary difference between Imran ('05) and Swoyer and Imran ('04) devices is that the Swoyer device and the Imran ('04) devices both implement an anchor mechanism, which punctures stomach tissue, while the Imran '05 device simply has an expanding tubular member to hold the electrodes in place. Imran '05 teaches a new method of holding the electrodes in place. Therefore, it would have been obvious to one of ordinary skill in the art to modify either the Swoyer device or the device of Imran ('04) in view of Imran ('05), in order to implement a less invasive means of attaching the electrodes to the gastrointestinal wall.

45. Claims 14, 31, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer (US 6,754,536) as discussed above, in view of Somdahl et al. (US 6,445,948). Somdahl teaches, "forming the battery to have a size corresponding with the shape of the electronics module. (Column 44, lines36-37). Somdahl further teaches, "forming the battery to have a shape corresponding with the shape of the electronics module." (Column 44, lines 41-

42). In view of these teachings, it would have been obvious for one of ordinary skill in the art to modify the Swoyer device to have a disc like battery in order to better fit the shape of the electronics module.

46. In regard to claims 14, 31, and 49, to merely change the shape would have been an obvious choice in design to one having ordinary skill in the art, absent any teaching of criticality or unexpected result.

47. Claims 22, 23, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer (US 6,754,536) and Imran (US 2004/0088023 A1) as discussed above. It is known in the art that waveforms of various frequencies and amplitudes are necessary to treat various disorders. Therefore, it would have been obvious to set the pulse generator to produce a waveform with an amplitude in a range of approximately 0.1mA -10mA, a frequency range of approximately 10Hz - 250Hz, a pulse width in a range of approximately 100μs - 1000μs, an on duty cycle in a range of approximately 0.1 – 0.5 seconds, and an off duty cycle in a range of approximately 1-10 seconds in order to achieve the desired results. Therefore, it would have also been obvious for one skilled in the art to set the pulse generator to produce a waveform with an amplitude of approximately 5mA, a frequency of approximately 14Hz, a pulse width of approximately 330 microseconds, an on duty cycle of approximately 0.1 seconds, with an off duty cycle of approximately 5 seconds in order to achieve the desired results.

48. Claims 18 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer (US 6,754,536) and as being unpatentable over Imran (US 2004/0088023 A1). Both Swoyer and Imran, as discussed above, disclose implantable gastrointestinal stimulation devices. Since these devices are developed for implantation into the body, it would be obvious to configure them to be as small as possible to make them less invasive to their environment.

Double Patenting

Claims 1, 2-5, 7,8, 9, 10, 11, 13, 14, 15, 19, 25-27, 30, 31, 32, 34, 35, 36, 37, 38, 39, 45, and 46 are rejected under the judicially created doctrine of obviousness-type double patenting.

49. In regard to claim 1, the current application claims a device that can be introduced into the GI tract, contains an electrical pulse generator, mounted within the device housing to generate an electrical stimulation waveform. It further claims one or more electrodes electrically coupled to the electrical pulse generator and mounted to the device to deliver electrical stimulation. It further discloses that a fixation structure is provided to attach the device to a surface of the GI tract. Claim 1 of US 6,754,536 claims an implantable GI tract medical device that can be affixed to the mucosal or submucosal layers. It also claims a hermetically sealed housing enclosing circuitry and a power source. Claim 3 claims that the device of claim 1 has an electrical conductor extending from the stimulation/sense electrode to the circuitry within the hermetically sealed housing.

50. In regard to claim 2, it would have been obvious to simply change the shape of the device housing to take on a capsule like shape.

51. In regard to claims 3, 4, 5, and 26, it would have been obvious to modify the Swoyer (US 6,754,536) device in view of claims 10, 11, 55, 56, 65, and 66 of Kilcoyne (US 2005/0043601 A1). Swoyer and Kilcoyne are discussed above. Swoyer teaches an implantable gastrointestinal stimulation device in which the attachment device is not on the device housing, but the attachment mechanism can function as a stimulation/sensing electrode. Kilcoyne teaches a sensing probe that can be implanted into the body lumen (such as the GI tract) and contains an attachment mechanism (with a pin) on the housing surface. Therefore, it would have been obvious to one of ordinary skill in the art to modify the Swoyer device in view of the Kilcoyne device in order to make the device smaller and less invasive.

52. Claims 1, 7, 8, 9, 10, 11, 15, 27, and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, and 12 of U.S. Patent No. 6,754,536. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the current application and claims 1 and 3 of US 6,754,536 have already been discussed. Claim 7 of the current application claims, "The device of claim 1, wherein the fixation structure includes one or ore barbed hooks that extend from the device housing to penetrate gastrointestinal tissue". Claim 8 of the current application claims "The device of claim 7, wherein the barbed hooks form at least

one of the electrodes." Claim 9 of the current application claims a fixation structure that includes a screw-like extension from the device housing to penetrate the gastrointestinal housing. Claim 10 of the current invention claims that the screw-like extension of claim 9 forms one of the electrodes. Furthermore, claim 11 claims that the screw-like extension of the device of claim 9 extends from the distal end of the housing. Finally, claim 15 of the current application claims, " The device of claim 1, wherein the fixation structure forms one of the electrodes. Claim 12 of US 6,754,536 claims, "The implantable medical device of Claim 1, wherein:

The free end of the elongated flexible member comprises an electrode head supporting the active fixation mechanism and supporting a stimulation/sense electrode and an electrical conductor extending from the stimulation/sense electrode to the circuitry within the hermetically sealed housing; and the circuitry comprises an electrical stimulation generator that supplies electrical stimulation of the GI tract wall through the stimulation/sense electrode.

53. In regard to claim 13 see claim 1 of US 5,754,536.

54. In regard to claims 14 and 31, it would have been obvious to simply change the shape of the battery to a disc-like shape.

55. In regard to claim 19 see claim 2 of U.S. Patent No. 6,754,536. Claim 19 of the current application claims "The device of claim 1, wherein the fixation structure is degradable to permit detachment of the housing..." Claim 2 of US 5,754,536 claims "The implantable device of claim 1, wherein the fixation mechanism is

formed of a material that dissolves over a period of time to release the implantable medical device."

56. In regard to claim 25, see claims 1 and 3 of US 5,754,536. Furthermore, it would have been obvious to set the pulse generator to establish a waveform that would suppress the symptoms of nausea and vomiting, two common gastrointestinal side effects of various medical procedures. These symptoms are also commonly occurring with certain gastrointestinal diseases.

57. In regard to claim 30, see claim 1, as well as #56 of this detailed action.

58. In regard to claim 32, see #56 of this action, along with #52 of this action.

59. In regard to claim 34, see claim 2, along with #56 of this detailed action.

60. In regard to claims 35, 36, and 37, see #56 of this detailed action. Furthermore, it is known that various voltages and frequencies must be applied to treat various disorders.

61. In regard to claims 39 and 40, the applicants claim a method for electrical stimulation of the GI tract comprising: placing an electrical stimulation device at the target location in the GI tract by endoscopic means through the esophagus and attaching the device to the target site through the implementation of a fixation structure. Claim 26 of US 6,754,536 claims a method of implanting a gastrointestinal implantable medical device by "...inserting the IMD into the lumen of an esophageal catheter body thereby restraining the flexible member and substantially reducing the bend; advancing the esophageal catheter body through the esophagus to locate the active fixation mechanism at an attachment

site of the GI tract wall within the GI tract; fixing the active fixation mechanism to the GI tract wall at the attachment site; and ejecting the IMD from the esophageal catheter lumen to enable the formation..."

62. In regard to claims 45 and 46, Swoyer discloses (in claim 27), "The method of claim 26, wherein the active fixation mechanism comprises a helix adapted to be screwed into the mucosa or sub-mucosal layers of the GI tract". In regard to claim 46, also see claim 12.

Conclusion

63. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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JEFFREY R. JASTRZAB
PRIMARY EXAMINER
8/23/05